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PATENT
ATTORNEY DOCKET NO. SHIM1120

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Aizawa et al.
Application No.: 09/830,019
Filing Date: September 21, 2001
Title: VACCINE PREPARATIONS CONTAINING ATTENUATED TOXIN

Art Unit: 1642
Examiner: Unassigned

#8
CFR Reg.
3/13/02

Commissioner for Patents
Office of Initial Patent Examination
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Washington, D.C. 20231

CFR
process
3/13/02

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TRANSMITTAL LETTER

Sir:

Transmitted herewith for filing in connection with the above-identified patent application,
please find the following:

- (1) Request for Correction of Notice of Acceptance of Application; (2 pgs)
- (2) Copy of Response to Notification of Missing Requirements Transmittal; (2 pgs)
- (3) Copy of Express Mail Receipt dated 9/21/01; (1 pg)
- (4) Copy of Postcard dated 9/21/01 Responding to Notification of Missing Requirements; (1 pg) and
- (5) Return postcard.

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are
being deposited with the United States Postal Service as first class
mail on this date, 2-7-02, in an envelope addressed to:
Commissioner for Patents, Washington, D.C. 20231

Yinia Nagar
(Name of Person mailing Paper)

[Signature] 2-7-02
(Signature of Person Mailing Paper) Date

In re Application of:

Aizawa, et al.

Application No.: 09/830,019

Filing Date: September 21, 2001

Page 2

PATENT

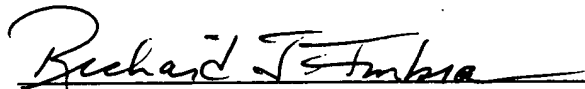
Attorney Docket No.: SHIM1120

No fee is deemed necessary in connection with the filing of this paper. However, if any fee is required, the Commissioner is hereby authorized to charge the amount of this fee, or credit any overpayments, to Deposit Account No. 50-1355. A copy of this Transmittal Letter is enclosed.

Respectfully submitted,

Date:

February 7, 2002



Richard J. Imbra

Registration No. 37,643

Telephone: (858) 677-1496

Facsimile: (858) 677-1465

USPTO CUSTOMER NO. 28213

GRAY CARY WARE & FREIDENRICH LLP

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San Diego, California 92121-2133



COPY OF PAPERS
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PATENT
Attorney Docket No.: SHIM1120

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Aizawa, et al. Art Unit: Unassigned
Application No.: 09/830,019 Examiner: Unassigned
IA Filing Date: October 20, 1999
Title: VACCINE PREPARATIONS CONTAINING ATTENUATED TOXIN

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**RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER
35 U.S.C. 371 IN THE UNITED STATES DESIGNATED / ELECTED OFFICE**

Sir:

In response to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated / Elected Office mailed May 22, 2001, enclosed are:

1. A copy of the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated / Elected Office (1 page);
2. An executed Declaration For Patent Application (5 pages);
3. An executed Power of Attorney by Assignee (1 page);
4. An executed Power of Attorney by Inventor (3 pages);
5. Petition for Two Month Extension of Time (2 pages);
6. Check in the amount of \$520.00;
7. Return Receipt Postcard.

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"EXPRESS MAIL" Mailing Label Number: EL617042227US
Date of Deposit: September 21, 2001

I hereby certify under 37 CFR§ 1.10 that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office To Addressee" with sufficient postage on the date indicated above and is addressed to Box Patent Application, Commissioner for Patents, Washington, DC 20231.


Mikhail Bayley

In re Application of:
Aizawa, et al.
Application No.: 09/830,019
IA Filing Date: October 20, 1999
Page 2

PATENT
Atty Docket No.: SHIM1120

XX Enclosed is a check in the total amount of \$520.00 which includes \$390.00 as two month extension of time fee and \$130.00 as payment for the surcharge fee for missing requirements of the application. The Commissioner is hereby authorized to charge any other fees that may be associated with this communication, or credit any overpayment to Deposit Account No. 50-1355. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Date: September 21, 2001



Lisa A. Haile, J.D., Ph.D.
Registration No.: 38,347
Telephone: (858) 677-1456
Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP
4365 Executive Drive, Suite 1600
San Diego, California 92121-2189
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COPY OF PAPER
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Applicants: Aizawa et al. Art Unit: 1642
Application No.: 09/830,019 Examiner: Unassigned
Filing Date: September 21, 2001
Title: VACCINE PREPARATIONS CONTAINING ATTENUATED TOXIN

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Customer Service Center
Washington, D.C. 20231

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TRANSMITTAL LETTER

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please find the following:

- (1) Request for Correction of Filing Receipt; (2 pgs)
- (2) Copy of Filing Receipt reflecting changes; (2 pgs)
- (3) Copy of Express Mail Receipt dated 9/21/01; (1 pg)
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- (5) Copy of Response to Notification of Missing Requirements Transmittal; (2 pgs) and
- (6) Return postcard.

CERTIFICATION UNDER 37 CFR §1.8	
I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, <u>2-14-02</u> , in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231	
<u>Yinia Nazar</u>	
(Name of Person mailing Paper)	
<u>[Signature]</u>	<u>2-14-02</u>
(Signature of Person Mailing Paper)	Date

In re Application of:
Aizawa et al.
Application No.: 09/830,019
Filing Date: September 21, 2001
Page 2

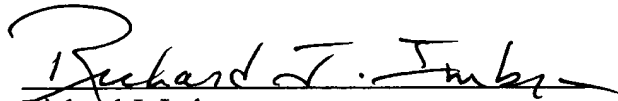
PATENT
Attorney Docket No.: SHIM1120

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Respectfully submitted,

Date:

February 7, 2002



Richard J. Imbra

Registration No. 37,643

Telephone: (858) 677-1496

Facsimile: (858) 677-1465

USPTO CUSTOMER NO. 28213

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San Diego, California 92121-2133

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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/830,019	Chikara Aizawa	SHIM1120

INTERNATIONAL APPLICATION NO.

PCT/JP99/05789

I.A. FILING DATE	PRIORITY DATE
10/20/1999	10/21/1998

28213

GARY CARY WARE & FRIENDENRICH LLP
 4365 EXECUTIVE DRIVE
 SUITE 1600
 SAN DIEGO, CA 92121-2189

CONFIRMATION NO. 9316

371 ACCEPTANCE LETTER



Date Mailed: 10/10/2001

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.494 OR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as an Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

09/12/2001
 DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2)
 and (c)(4) REQUIREMENTS

09/12/2001
 DATE OF RECEIPT OF ALL 35 U.S.C.
 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- U.S. Basic National Fee
- Copy of IPE Report
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report
- Oath or Declaration
- Preliminary Amendments
- Request for Immediate Examination

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

TAMALA D HOLLAND

Telephone: (703) 305-5483

PART 1 - ATTORNEY/APPLICANT COPY

DATE MAILED: SEPTEMBER 21, 2001

PATENT ATTORNEY DOCKET NO.: SHIM1120

The Patent and Trademark Office date stamp sets forth the receipt date of:

Applicant or Patentee: Aizawa, et al.

IA Filing Date: October 20, 1999

Serial No.: 09/830,019

Title: VACCINE PREPARATIONS CONTAINING ATTENUATED TOXIN

**RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371
IN THE UNITED STATES DESIGNATED / ELECTED OFFICE**

1. Transmittal Letter [2 pgs, in dup.];
2. Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated / Elected Office [1 pg];
3. Declaration [5 pgs];
4. Power of Attorney by Assignee [1 pg];
5. Power of Attorney by Inventor [3 pgs.];
6. Petition for Two Month Extension of Time [2 pgs., in dup.];
7. Check in the amount of \$520.00

[Spaced Reserved For PTO Stamp]

Atty/Sec Initials: LAH/kdl

Client/Matter No.: 2102595-3

Date Mailed: 09/21/01

Date Due: 09/21/01

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SAN DIEGO, CA 92101-4297

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74-478/724

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DATE 09/21/01

AMOUNT OF CHECK
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ORDER OF

COMMISSIONER OF PATENTS & TRADEMARKS

Henry M. Th...
Susan Plummer
VOID AFTER 180 DAYS

EXPLANATION OF ADDITIONAL SECURITY FEATURES INDICATED ON REVERSE SIDE

⑈489989⑈ ⑆072404786⑆ 2176989081⑈



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PATENT
ATTORNEY DOCKET NO. SHIM1120

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Aizawa et al.
Application No.: 09/830,019
Filing Date: September 21, 2001
Title: VACCINE PREPARATIONS CONTAINING ATTENUATED TOXIN

Art Unit: 1642
Examiner: Unassigned

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REQUEST FOR CORRECTION OF FILING RECEIPT

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Sir:

This Communication is submitted to request correction of the filing receipt in reference to the above-identified application. The data requiring correction is indicated in yellow highlight on the attached copy of the filing receipt and herein in **BOLD**.

Please change the filing date from "September 12, 2001" to **September 21, 2001**.

Applicants accordingly request the correction be made of record.

CERTIFICATION UNDER 37 CFR §1.8	
I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, <u>2-7-02</u> , in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231	
<u>Vinia Najjar</u> (Name of Person mailing Paper)	
<u>[Signature]</u> (Signature of Person Mailing Paper)	<u>2-7-02</u> Date

In re Application of:
Aizawa et al.
Application No.: 09/830,019
Filing Date: September 21, 2001
Page 2

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Attorney Docket No.: SHIM1120

No fee is deemed necessary in connection with the filing of this paper. However, if any fee is required, the Commissioner is hereby authorized to charge the amount of this fee, or credit any overpayments, to Deposit Account No. 50-1355.

Respectfully submitted,

Date:

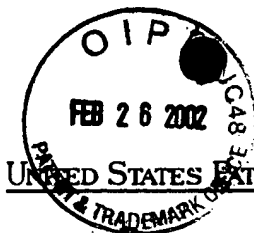
February 7, 2002

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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/830,019	09/12/2001	1642	990	SHIM1120	5	12	1

28213

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4365 EXECUTIVE DRIVE
SUITE 1600
SAN DIEGO, CA 92121-2189

CONFIRMATION NO. 9316

FILING RECEIPT



OC000000006835005

Date Mailed: 10/10/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Chikara Aizawa, Saitama, JAPAN;
Yujiro Suzuki, Saitama, JAPAN;
Taka-aki Sato, Saitama, JAPAN;
Koji Watanabe, Saitama, JAPAN;
Nobuaki Hattori, Saitama, JAPAN;
Yoshitake Tanaka, Saitama, JAPAN;
Satoshi Omura, Tokyo, JAPAN;

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Domestic Priority data as claimed by applicant

THIS APPLICATION IS A 371 OF PCT/JP99/05789 10/20/1999

Foreign Applications

JAPAN 10/300219 10/21/1998

Projected Publication Date: Not Applicable, filed prior to November 29,2000

Non-Publication Request: No

Early Publication Request: No

Title

Vaccine preparations containing attenuated toxin

Preliminary Class

514

FEB 26 2002



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LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15 (b).

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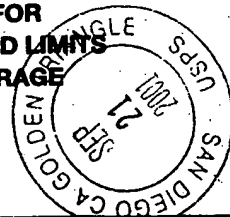


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The Patent and Trademark Office date stamp sets forth the receipt date of:

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6. Petition for Two Month Extension of Time [2 pgs., in dup.];
7. Check in the amount of \$520.00

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Atty/Sec Initials: LAH/kdl

Client/Matter No.: 2102595-3

Date Mailed: 09/21/01

Date Due: 09/21/01

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SAN DIEGO, CA 92101-4297

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Comerica Bank & Trust, NA

74-478/724

CHECK NO. 489989

DATE 09/21/01

AMOUNT OF CHECK
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ORDER OF

COMMISSIONER OF PATENTS & TRADEMARKS

Handwritten signature: Raymond M. Th...
Handwritten signature: Susan D. Plummer
VOID AFTER 180 DAYS

EXPLANATION OF ADDITIONAL SECURITY FEATURES INDICATED ON REVERSE SIDE

⑈489989⑈ ⑆072404786⑆ 2176989081⑈

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